

## RESPONSE TO OFFICE ACTION

### A. Status of the Claims

Claims 1-23 were originally filed with the application. Claims 24-26 were added. Claims 13 and 19-23 were withdrawn from consideration as directed to a non-elected invention. Claims 5-9, 12, 14, 16-18, and 24 were cancelled. Claims 13, 15, and 19 have been amended to correct typographic errors. Support for the amendment of claim 15 is found in the Specification, for instance at page 6, lines 7-9. No new matter is added. Claims 1-4, 10, 11, 15, 25, and 26 are submitted herein for reconsideration.

### B. Rejections Under 35 U.S.C. §103

The Action maintains the rejection of claims 1-4, 10, 11, 15, 25, and 26 as obvious over Heim *et al.* (U.S. Patent Application Publication No. 2003/0188345A1, filed June 28, 2001), in view of Lange *et al.* (U.S. Patent No. 5,939,539) and Ebinuma *et al.* 1997 (*Proc. Natl. Acad. Sci. USA* 94:2117-2121). Specifically, the Action states that Heim *et al.* disclose use of a plant cell non-lethal negative selectable marker (*e.g. codA*) in vector backbone DNA for combined positive/negative selection, Lange *et al.* teach a plant hormone degradative/modifying gene as a selectable marker, and Ebinuma *et al.* teach use of the isopentenyl transferase gene (*ipt*) as a selectable marker. Thus it is again asserted that it would have been *prima facie* obvious for one of skill in the art to modify the teachings of Heim *et al.* with those of Lange *et al.* and Ebinuma *et al.* Applicants respectfully traverse.

Applicants first respectfully note that Heim, in discussing use of *codA* of Gallego at paragraph [0023], is describing the use of a (conditional) lethal negative selectable marker gene, and not a non-lethal negative selectable marker gene as is claimed. That is, in the presence of

added 5-fluorocytosine (5-FC), the *codA* gene product functions as a lethal negative selectable marker, while in the absence of 5-FC, the *codA* gene does not function as a selectable marker. This is also discussed in the Specification, for instance at page 3, line 10 and following, relating to use of conditional lethal gene products, which are distinguishable in the art from non-lethal negative selectable marker gene products. Thus, contrary to the assertion in the Action at page 5, 2<sup>nd</sup> paragraph, Applicants submit that Heim does not teach “...the basic structure of claim 1” when all claim limitations are considered (M.P.E.P. 2143.03).

**1. The Assertion of Unexpected Results is Commensurate With the Scope of the Claims.**

Applicants also bring to the Examiner’s attention the Information Disclosure Statement and accompanying reference (Ye *et al.*, *Transgenic Res.* 17:827-838, 2008). Applicants respectfully submit that the data described in Ye *et al.*, for instance at FIG. 2 on page 832, demonstrate that ***unexpected results*** relating to the effect of the presence of a gibberellic acid pathway substrate-diverting gene, in inhibiting regeneration of transgenic plants that contain backbone sequences (FIG. 2B), and leading for instance to an unexpected increase in the percentage of single-copy transformants (FIG. 2C), ***are commensurate with the scope of the present claims***. That is, such unexpected results are not found only with use of a phytoene synthase gene (*crtB*), but also when another gibberellic acid pathway substrate-diverting gene, encoding GA 2-oxidase, was utilized.

**2. Applicants’ Arguments Relating to Heim as Teaching Use of a Non-lethal Negative Selectable Marker Have Not Yet Been Fully Addressed.**

The Action asserts that it would have been *prima facie* obvious to modify the teachings of Heim to use other negative selectable marker genes such as those taught by Lange or Ebinuma,

Applicants respectfully maintain that the assertion that Heim motivates the use of “any” non-lethal selectable marker, let alone “other” non-lethal selectable markers, is unsupported and represents hindsight reasoning. Applicants respectfully again ask that the Examiner point to any teaching of Heim that relates to use of a (or indeed “any”) non-lethal negative selectable marker gene. As noted above, the teachings of Heim specifically regarding a negative selectable marker are found in one sentence at paragraph [0023], and the gene discussed, *codA*, encodes a conditional lethal negative selectable gene product, and not a non-lethal negative selectable gene product.

**3. Ebinuma is not Apt.**

Applicants further respectfully submit that the relevance of Ebinuma, which relates to use of an *ipt* gene active in cytokinin synthesis, ***but not in gibberellic acid synthesis or substrate diversion***, is obviated by a previous amendment to the claims in the response of July 18, 2008, which for instance removed the limitation “plant hormone biosynthesis pathway” that had been found in claim 1 and added the term “gibberellic acid pathway substrate diverting gene.” Thus Ebinuma is not apt.

**4. Lange Teaches Away From Use of GA 20-Oxidase as Presently Claimed, and is Not Properly Combined with Heim.**

As noted previously, Lange does not describe use of gibberellin 20-oxidase (GA 20-oxidase) as a ***selectable marker***, including its use as a non-lethal negative selectable marker. Rather, use of the GA 20-oxidase by Lange is in the context of its effect on plant growth characteristics due to up-regulation or down-regulation of GA synthesis (*e.g.* Lange, U.S. Patent 5,939,539; column 17, line 45, to column 18, line 34), including instances where GA 20-oxidation is a rate limiting step (Lange, column 18, lines 10-11). Applicants’ arguments in this

regard, although acknowledged in the pending action at page 4, line 3 and following, are not otherwise addressed in the Action. Thus, Applicants again respectfully submit that Lange *teaches away* from the presently claimed invention because, in view of Lange, given sequences involved in GA synthesis *are required to be present for an effect such as altered vegetative growth to be seen*. This teaches away from use of a GA 20-oxidase encoding sequence as a non-lethal negative selectable marker, since loss of a GA 20-oxidase transgene would be understood by the skilled practitioner, in view of Lange, to lead to loss of a desired phenotype, and would thus be avoided by a practitioner in view of the teachings of Lange. Further, combining the teachings of Heim with those of Lange, *i.e.* using GA 20-oxidase as a negatively selectable marker and selecting for loss of the GA 20-oxidase encoding sequence, would render the GA 20-oxidase of Lange unsatisfactory for its intended purpose in modifying growth or developmental processes in plants (*e.g.* Lange, column 17, lines 31-33). *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984); M.P.E.P. 2143.01 V. Thus, Lange is not properly combined with Heim.

Simply put, Lange in no way teaches suggests or contemplates that a GA20-oxidase or any other gene involved in GA synthesis is to be used as a non-lethal negatively selectable marker, for instance by placing the coding sequence outside of the border sequences on a vector designed for *Agrobacterium*-mediated transformation and then selecting for loss of the presence of the gene and associated vector sequence. Neither does Lange provide any motivation to construct such a vector, instead teaching away from the prospect at least insofar as use of a gene encoding GA 20-oxidase is concerned. In light of all the above, Applicants respectfully request that the rejection under 35 U.S.C. §103 be withdrawn.

**C.     Conclusion**

In light of the foregoing, applicants submit that all claims are in condition for allowance, and an early indication to that effect is earnestly solicited. The examiner is invited to contact the undersigned at (214) 259-0932 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,

/Ron J. Laby/

Ron J. Laby  
Reg. No. 53,173  
Agent for Applicants

Sonnenschein Nath & Rosenthal, L.L.P.  
2000 McKinney Ave., Suite 1900  
Dallas, Texas 75201-1858  
(214) 259-0900

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